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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Elazar Rabbani et al.

Serial No. 09/439,594

Group Art Unit: 1635

Filed: November 12, 1999

Examiner: Joyce Tung

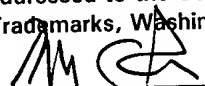
Title: DETECTING THE PRESENCE OF SPECIFIC  
TARGET NUCLEIC ACID SEQUENCES  
THROUGH STEM-LOOP FORMATION

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INFORMATION DISCLOSURE STATEMENTHON. COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

Sir:

Transmitted herewith is an Information Disclosure Statement which is being filed in accordance with 37 C.F.R. §§ 1.56 and 1.97-1.98. The items listed on Form PTO-1449, a copy of which is enclosed, may be deemed to be pertinent to the above-identified application and are made of record to assist the Patent and Trademark Office in its examination of this application. The Examiner is respectfully requested to fully consider the items and to independently ascertain their teaching.

EXPRESS MAIL CERTIFICATE	
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Deposit Date	January 22, 2003
I hereby certify that this paper and the attachments herein are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to the Commissioner of Patents and Trademarks, Washington DC 20231.	
	JAN 22 2003
Ronald C. Fedus Reg. No. 32,567	Date

1. ☐ For each of the following items listed on the enclosed copy of Form PTO-1449 that is not in the English language, an English language translation of that item or a portion thereof or a concise explanation of the relevance of that item is enclosed:
2. ☐ For each of the following items listed on the enclosed copy of form PTO-1449 that is not in the English language, a concise explanation of the relevance of that item is incorporated in the specification of the above-identified application.
3. ☐ Any copy of the items on the enclosed copy of Form PTO-1449 that is not enclosed with this Information Disclosure Statement was previously cited by or submitted to the Patent and Trademark Office in the prior ☐ Divisional or ☐ Continuation-In-Part application under 37 C.F.R. §1.60, U.S. Serial No. \_\_\_\_\_, filed \_\_\_\_\_.
4. ☐ No fee is due under 37 C.F.R. §1.17(p) for this Information Disclosure Statement since it is being filed in compliance with:
  - ☐ 37 C.F.R. §1.97(b)(1), within three months of the filing date of the above-identified application.
  - ☐ 37 C.F.R. §1.97(b)(2), within three months of the date of entry into the national stage as set forth in §1.491 in an international application.
  - ☐ 37 C.F.R. §1.97(b)(3), before the mailing date of a first Office action on the merits.
5. ☐ No fee is due under 37 C.F.R. §1.17(p) for this Information Disclosure Statement since it is being filed in compliance with 37 C.F.R. §1.97(c), after the period specified in paragraph 4 above but before the mailing date of a final action or a Notice of Allowance (where there has been no prior final action), and is accompanied by one of the certifications pursuant to 37 C.F.R. §1.97(e) set forth in paragraph 9 below.
6. ☒ A fee is due under 37 C.F.R. §1.17(p) for this Information Disclosure Statement since it is being filed in compliance with 37 C.F.R. §1.97(c), after the period specified in paragraph 4 above but before the mailing date of a final action or a notice of allowance (where there has been no prior final action):

☐ A check in the amount of \$240.00 is enclosed in payment of the fee.

☒ Charge the fee to Deposit Account No. 05-1135, Order No. ENZ-58.  
A DUPLICATE COPY OF THIS SHEET IS ATTACHED.

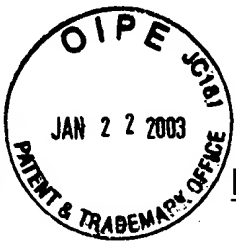
7. ☐ A fee is due under 37 C.F.R. §1.17(i)(1) for this Information Disclosure Statement since it is being filed in compliance with 37 C.F.R. §1.97(d), after the mailing date of a final action or a notice of allowance, whichever comes first, but before payment of the issue fee, and is accompanied by:

- a. one of the certification pursuant to 37 C.F.R. §1.97(e) set forth in paragraph 9 below; and
- b. the attached petition requesting consideration of this Information Disclosure Statement; and
- c. the fee due under 37 C.F.R. §1.17(i)(1) which is paid as set forth in paragraph 10 below.

8. ☐ A fee is due under 37 C.F.R. §1.17(i)(1) for this Information Disclosure Statement since it is being filed in compliance with:

- a. ☐ 37 C.F.R. §1.313(b)(3), after the issue fee has been paid and information cited in this Information Disclosure Statement may render at least one claim unpatentable and is accompanied by the attached Petition To Withdraw Application From Issue;
- b. ☐ 37 C.F.R. §1.313(b)(5), after the issue fee has been paid and information cited in this Information Disclosure Statement is to be considered in a Continuation application upon abandonment of the instant application and is accompanied by the attached Petition To Withdraw Application From Issue.
- c. ☐ The fee due under 37 C.F.R. §1.17(i)(1) is paid as set forth in paragraph 10 below.

9. ☐ I hereby certify that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.



**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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Applicants: Elazar Rabbani et al.

Serial No. 09/439,594

Filed: November 12, 1999

Title: **DETECTING THE PRESENCE OF SPECIFIC  
TARGET NUCLEIC ACID SEQUENCES  
THROUGH STEM-LOOP FORMATION**

Group Art Unit: 1635

Examiner: Joyce Tung

527 Madison Avenue, 9th Floor  
New York, NY 10022-4304  
January 22, 2003

**FILED BY EXPRESS MAIL**

Honorable Commissioner  
of Patents and Trademarks  
Washington, D.C. 20231

**INFORMATION DISCLOSURE STATEMENT  
UNDER 37 C.F.R. §§1.56 & 1.97-1.98**

Dear Sirs:

Pursuant to the provisions of 37 C.F.R. §§1.97-1.98, and in full compliance with their duty of disclosure under 37 C.F.R. §1.56, Applicants, through their attorney, are bringing the following forty-one (41) documents to the attention of the U.S. Patent and Trademark Office and the Examiner handling their above-identified application:

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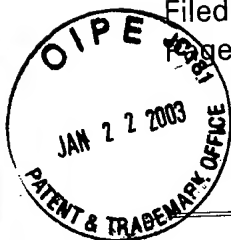
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Page 2 [Information Disclosure Statement Under 37 C.F.R. §§1.56 & 1.97-I.98  
-- January 22, 2003]

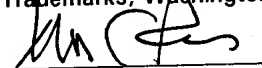


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Ronald C. Fedus  
Reg. No. 32,567

JAN 22 2003  
Date

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1. Saiki, R.K. et al., "Enzymatic Amplification of Beta-Globin Genomic Sequences and Restriction Site Analysis for Diagnosis of Sickle Cell Anemia," Science 230:1350-1354 (1985) [Exhibit 1];
2. Meyers, T.W. and Gelfand, D.H., "Reverse Transcription of DNA Amplification by a *Thermus thermophilus* DNA Polymerase," Biochemistry 30(31):7661-7666 (1991) [Exhibit 2];
3. Rose, R. et al., U.S. Patent No. 5,508,178 issued April 16, 1996 [Exhibit 3];
4. Rose R. and Western L.M., U.S. Patent No. 5,439,793 issued August 3, 1995 [Exhibit 4];
5. Rose R. et al., U.S. Patent No. 5,595,891 issued January 21, 1997 [Exhibit 5];
6. Western L.M. et al., U.S. Patent No. 5,612,199 issued March 18, 1997 [Exhibit 6];
7. Backman, E. C. and Wang C-N J., European Patent No. 0 302 308B1 granted 11/3/93 [Exhibit 7];
8. Landegren U. et al., "A Ligase-Mediated Gene Detection Technique," Science 241:1077 (1988) [Exhibit 8];
9. Wu D. and Wallace, R.B., "The Ligation of Amplification Reaction (LAR)-Amplification of Specific DNA Sequences Using Sequential Round of Template-Dependent Ligation," Genomics 4:560-569 (1989) [Exhibit 9];
10. Barany F., "Genetic disease detection and DNA amplification using cloned thermostable ligase," Proc. Natl. Acad. Sci. (USA) 88:189-193 (1991) [Exhibit 10];
11. Kwok D.Y. et al., "Transcription-based amplification system and detection of amplified human immunodeficiency virus type 1 with a bead-based sandwich hybridization format," Proc. Natl. Acad. Sci. (USA) 86:1173-1177 (1989) [Exhibit 11];

12. Kievits, T. et al., "NASBA™ isothermal enzymatic in vitro nucleic acid amplification optimized for the diagnosis of HIV-1 infection," Journal of Virological Methods 35:273-286 (1991) [Exhibit 12];
13. Walker, G.T. et al., "Isothermal in vitro amplification of DNA by a restriction enzyme/DNA polymerase system," Proc. Natl. Acad. Sci. (USA) 89:392-396 (1992) [Exhibit 13];
14. Walker G.T. et al., U.S. Patent No. 5,270,184 issued December 14, 1993 [Exhibit 14];
15. Saiki R.K. et al., "Primer-Directed Enzymatic Amplification of DNA with a Thermostable DNA Polymerase," Science 239:487-491 (1988) [Exhibit 15];
16. Auer, T. et al., "Selective amplification of RNA utilizing the nucleotide analog dITP and *Thermus thermophilus* DNA polymerase," Nucleic Acids Research 24(24):5021-5025 (1996) [Exhibit 16];
17. Maxam A. M. and Gilbert, W., "A new method for sequencing DNA," Proc. Natl. Acad. Sci. (USA) 74(2):560-564 (1977) [Exhibit 17];
18. Sanger F., et al., "DNA sequencing with chain-terminating inhibitors," Proc. Natl. Acad. Sci. (USA) 74(12):5463-5467 (1977) [Exhibit 18];
19. Engelhardt D., et al., U.S. Patent No. 5,241,060 issued August 31, 1993 [Exhibit 19];
20. Beck S., et al., "Chemiluminescent detection of DNA: application for DNA sequencing and hybridization," Nucleic Acids Research 17(13):5115-5123 (1989) [Exhibit 20];
21. Ansorge W., et al., "A non-radioactive automated method for DNA sequence determination," Journal of Biochemical and Biophysical Methods 13:315-323 (1986) [Exhibit 21];
22. Sequenase Images™ Protocol Book , United States Biochemical Corporation, Cleveland, Ohio, pages 106-107 (1993) [Exhibit 22];

23. Hobbs, F.W. and Cocuzza, A.J., U.S. Patent No. 5,047,519 issued Sep. 10, 1991 [Exhibit 23];
24. Middendorf L., and Braumbaugh, J.A., U.S. Patent No. 4,729,947 issued March 3, 1988 [Exhibit 24];
25. Morii, K. et al., U.S. Patent No. 5,027,880 issued July 2, 1991 [Exhibit 25];
26. Middendorf L., and Patonay G., U.S. Patent No. 5,346,603 issued September 13, 1994 [Exhibit 26];
27. Middendorf L., and Patonay G., U.S. Patent No. 5,230,781 issued July 24, 1993 [Exhibit 27];
28. Middendorf L. R. et al., U.S. Patent No. 5,360,523 issued November 1, 1994 [Exhibit 28];
29. Smith, L.M. et al., U.S. Patent No. 5,171,534 issued December 15, 1992 [Exhibit 29];
30. Prober J.M. et al., U.S. Patent No. 5,332,666 issued July 26, 1994 [Exhibit 30];
31. Beck S., "Colorimetric-Detected DNA Sequencing," Methods in Enzymology 184:612-617 (1990) [Exhibit 31];
32. Coassin P.J. et al., U.S. Patent No. 5,462,854 issued October 31, 1995 [Exhibit 32];
33. Wetmur J.G., "DNA Probes: Applications of the Principles of Nucleic Acid Hybridization," Critical Reviews in Biochemistry and Molecular Biology 26(3/4):227-259 (1991) [Exhibit 33];
34. Kornberg A. and Baker T.A., DNA Replication, 2<sup>nd</sup> Edition, W.H. Freeman and Co., New York, New York, pages 44-46 (1992) [Exhibit 34];
35. Adams, R.L.P. et al., The Biochemistry of the Nucleic Acids, Chapman & Hall, London, U.K., page 31 (1992) [Exhibit 35];



36. Stavrianopoulos, J and Rabbani, E., et al., EP0 231 495B1 granted June 16, 1999 [Exhibit 36];
37. Prober J.M., et al., "A System for Rapid DNA Sequencing with Fluorescent Chain-Terminating Dideoxynucleotides,": Science 238:336-341 (1987) [Exhibit 37];
38. Ward, D.C. et al., U.S. Patent No. 5,476,928 issued December 19, 1995 [Exhibit 38];
39. Engelhardt D. et al., U.S. Patent No. 5,260,433 issued November 9, 1993 [Exhibit 39];
40. Stavrianopoulos J.G., U.S. Patent No. 4,707,440 issued November 17, 1987 [Exhibit 40]; and
41. Kornberg A. and Baker T.A., DNA Replication, 2<sup>nd</sup> Edition, W.H. Freeman and Co., New York, New York, pages 447-449 (1992) [Exhibit 41].

The above documents [Exhibits 1-41] were cited in the instant specification.

A completed Form PTO-1449 listing the 41 above-submitted documents is also attached hereto as Exhibit A.

By this voluntary citation of art, Applicants and their attorney are requesting that the documents be made of record in the present application.

The above citation of documents is not a representation that these documents constitute a complete or exhaustive listing, nor that the above listing necessarily includes the closest or most relevant documents, nor are these documents necessarily a complete listing of all documents known to Applicants or their attorney. It is simply a voluntary citation of documents made in good faith, which is not intended to serve in any way as a substitute for the Examiner's own search.

In view of the general and specific features described and claimed in the present application, Applicants respectfully submit that the present invention is

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Page 7 [Information Disclosure Statement Under 37 C.F.R. §§1.56 & 1.97-I.98  
-- January 22, 2003]

neither disclosed nor suggested by the documents referred to above and is thus patentably distinct thereover. Furthermore, Applicants do not believe, and do not submit, by the citation of these references, that these documents, either by themselves or in combination with other documents, render the invention *prima facie* obvious under the duty of disclosure rules.

Applicants respectfully request that the Examiner make the above-submitted documents of record in the instant application. Applicants further request that the Examiner consider these documents as any of them may relate to the instant application.

The fee under 37 C.F.R. §1.17(p) for filing this Information Disclosure Statement is \$180.00. The Patent and Trademark Office is hereby authorized to charge the amount of this fee (and any other fees in connection with this IDS) to Deposit Account No. 05-1135, or to credit any overpayment thereto.

Respectfully submitted,

  
Ronald C. Fedus

Registration No. 32,567

Attorney for Applicants

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